



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,337	04/19/2004	Jorg Senn-Bilfinger	25079Y	9566

34375 7590 12/07/2005

NATH & ASSOCIATES PLLC
112 South West Street
Alexandria, VA 22314

EXAMINER

RAHMANI, NILOOFAR

ART UNIT	PAPER NUMBER
----------	--------------

1625

DATE MAILED: 12/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/826,337	Applicant(s) SENN-BILFINGER ET AL.	
	Examiner Niloofar Rahmani	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 10/182,619.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-10 are currently pending in the instant application.

Priority

2. This application is a 371 of PCT/EP01/03514, filed on 03/28/2001, which claims the priority of EP 00106695, filed on 03/29/2000. The priority document, however, is not in the file.

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

3. ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-10 are rejected because the definition for R4' and R5' is vague and unclear. What groups are encompassed by the "radical from which a hydroxyl group is formed under physiological conditions"? It is recommended that the chemical names or structures be recited in the compound claim.

Claims 2-7 are rejected because -OR' has no antecedent basis in the base claim 1. Inclusion in claim 1 is recommended.

Art Unit: 1625

4. Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 10 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. V. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

5. Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S.

1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

Art Unit: 1625

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-10 are rejected under 103(a) as being unpatentable over Senn-Bilfinger et al. US 6160119 or US 6197783 in view of Bundgaard et al. DE 4308095, Schulte et al. US 5432183, and Aungst US 4673679.

Determination of the scope and content of the prior art (MPEP §2141.01)

Senn-Bilfinger in US 6,160,119 disclosed a fused dihydropyran compound useful for treatment of gastrointestinal diseases. See columns 1-2 and column 22, claim 1. Specific examples are described in columns 5-6, Table 1 and on column 24, claims 6-7. Senn-Bilfinger in US 6,197,783 disclosed a tetrahydroimidazonaphthyridine compound useful for treatment of gastrointestinal diseases. See columns 1-2 and columns 25-26, claim 1. Specific examples are described in columns 5-6, table 1 and on columns 27-28, claims 6-7.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the prior art compounds is that Senn-Bilfinger compounds in the tables have R' substituted a hydroxyl whereas the instant claims have a radical from which a hydroxyl group is formed under physiological conditions, such as the methyl carboxylate, ethyl carboxylate etc. as recited in the instant claims 5,8. The instant claims are therefore the prodrug of the hydroxy compounds of Senn-Belfinger et al. The preparation of the prodrug for enhanced solubility, delivery, and other pharmacokinetics is well known in the pharmaceutical art. It is generally taught by Bundgaard on the page 1

Art Unit: 1625

and 3, table 2 and specifically shown for various hydroxyl containing compounds, as in DE 4308095 (see English abstract), Schulte (5432183, see column 2, lines 9-39) and Aungst (4673679, see columns 11-12, table 1) wherein the prodrug of hydroxymorphinan lacks the bitter taste of the parent compound and enhances its bioavailability (abstract).

Finding of prima facie obviousness-rational and motivation (MPEP §2142.2143)

One having ordinary skill in the art would have been motivated to prepare the prodrug of the hydroxyl compound of Sen-Bilfinger et al. as taught by Bundgaard, DE 4308095, Schulte, US 5432183, and Aungst US 4673679 to arrive at the instant invention for enhanced delivery of the drug compounds.

6. *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S.

1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

Art Unit: 1625

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-10 are rejected under 103(a) as being obvious over Grundler et al. (WO 98/54188), or Simon et al. WO 98/42707 in view of Bundgaard et al. DE 4308095, Schulte et al. US 5432183, and Aungst US 4673679.

Determination of the scope and content of the prior art (MPEP §2141.01)

Grundler disclosed a fused dihydropyran compound useful for treatment of gastrointestinal diseases on the pages 1-2, and page 26, claim 1. Specific examples are described in pages 6-7, table 1 and on page 28, claim 6-7. Simon generically disclosed a tetrahydroimidazonaphthyridine compound useful for treatment of gastrointestinal diseases on the pages 1-2 and page 33, claim 1. Specific examples are described in pages 6-7, table 1.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the prior art compounds is that Grundler and Simon compounds in the tables have R' substituted a hydroxyl whereas the instant claims have a radical from which a hydroxyl group is formed under physiological conditions, such as the methyl carboxylate, ethyl carboxylate etc. as recited in the instant claims 5,8. The instant claims are therefore the prodrug of the hydroxy compounds of Grundler and Simon. The preparation of the prodrug for

Art Unit: 1625

enhanced solubility, delivery, and other pharmacokinetics is well known in the pharmaceutical art. It is generally taught by Bundgaard on the page 1 and 3, table 2 and specifically shown for various hydroxyl containing compounds, as in DE 4308095 (see English abstract), Schulte (5432183, see column 2, lines 9-39) and Aungst (4673679, see columns 11-12, table 1) wherein the prodrug of hydroxymorphinan lacks the bitter taste of the parent compound and enhances its bioavailability (abstract).

Finding of prima facie obviousness-rational and motivation (MPEP §2142.2143)

One having ordinary skill in the art would have been motivated to prepare the prodrug of the hydroxyl compound of Grundler and Simon as taught by Bundgaard, DE 4308095, Schulte, US 5432183, and Aungst US 4673679 to arrive at the instant invention for enhanced delivery of the drug compounds.

7. Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383

U.S.

Art Unit: 1625

1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-10 are rejected under 103(a) as being obvious over Senn-Bilfinger et al. (WO 00/26217), in view of Bundgaard et al. DE 4308095, Schulte et al. US 5432183, and Aungst US 4673679.

Determination of the scope and content of the prior art (MPEP §2141.01)

Senn-Bilfinger disclosed tetrahydroimidazonaphthyridine compound useful for treatment of gastrointestinal diseases on the pages 1-5 and page 34-35, claim 1. Specific examples are described in pages 13-23, table 1.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the prior art compounds is that Senn-Bilfinger compounds in the tables have R' substituted a hydroxyl whereas the instant claims have a radical from which a hydroxyl group is formed under physiological conditions, such as the methyl carboxylate, ethyl carboxylate etc. as recited in the instant claims 5,8. The instant claims are therefore the prodrug of the hydroxy compounds of senn-Bilfinger. The preparation of the prodrug for enhanced solubility, delivery, and other pharmacokinetics is well known in the

Art Unit: 1625

pharmaceutical art. It is generally taught by Bundgaard on the page 1 and 3, table 2 and specifically shown for various hydroxyl containing compounds, as in DE 4308095 (see English abstract), Schulte (5432183, see column 2, lines 9-39) and Aungst (4673679, see columns 11-12, table 1) wherein the prodrug of hydroxymorphinan lacks the bitter taste of the parent compound and enhances its bioavailability (abstract).

Finding of prima facie obviousness-rational and motivation (MPEP §2142.2143)

One having ordinary skill in the art would have been motivated to prepare the prodrug of the hydroxyl compound of Senn-Bilfinger as taught by Bundgaard, DE 4308095, Schulte, US 5432183, and Aungst US 4673679 to arrive at the instant invention for enhanced delivery of the drug compounds.

8. *Claim Rejections - Obvious Double Patenting*

Claims 1-10 are rejected under the judicially created doctrine obviousness-type double patenting as being unpatentable over claims 1-7 of US 6,916,825. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current invention claims are embraced by the invention claimed in the above patent.

Determination of the scope and content of the prior art (MPEP §2141.01)

Senn-Bilfinger in US 6,916,825 claimed analogous compounds useful for treatment of gastrointestinal diseases.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

Art Unit: 1625

The difference between the instant claims and the prior art compounds is that Senn-Bilfinger in the prior art has hydrate, solvent, salt, hydrate of a salt or solvent of a salt rather than salt in the instant case.

Finding of prima facie obviousness-rational and motivation (MPEP §2142.2143)

The instant claims 1-10 are therefore fully embraced by the prior art claims 1-7.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 168 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130 (b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. *Claim Rejections - Obvious Double Patenting*

Claims 1-10 are rejected under the judicially created doctrine obviousness-type double patenting as being unpatentable over claims 1-9 of US 6,384,048. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current invention claims are embraced by the invention claimed in the above patent.

Determination of the scope and content of the prior art (MPEP §2141.01)

Art Unit: 1625

Senn-Bilfinger in US 6,384,048 claimed
tetrahydroimidazonaphthyridine compound useful for treatment of
gastrointestinal diseases.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the issued claims is that the
instant claims are fully embraced by the issued claims 1-9 of the
US 6,384,048, i.e. when R8 is hydrogen of the issued claims.

Finding of prima facie obviousness-rational and motivation (MPEP §2142.2143)

There is no good reason why the issued scope should be given
continuous exclusivity in the broad scope of the instant claims.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, In re Thorington, 418 F.2d 528, 168 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130 (b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. *Claim Rejections - Obvious Double Patenting*

Claims 1-10 are rejected under the judicially created doctrine
obviousness-type double patenting as being unpatentable over claims 1-
10 of US 6,160,119 or the claims 1-14 of US 6,197,783 in views of

Art Unit: 1625

Bundgaard (DE 4308095), Schulte and Aungst for reasons set forth in paragraph 5 above.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 168 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130 (b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. *Claim Rejections - Obvious Double Patenting*

Claims 1-10 are rejected under the judicially created doctrine obviousness-type double patenting as being unpatentable over claims 1-13 of US 6,436,953 in view of Bundgaard et al. DE 4308095, Schulte et al. US 5432183, and Aungst US 4673679. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current invention claims are embraced by the invention claimed in the above patent.

Determination of the scope and content of the prior art (MPEP §2141.01)

Senn-Bilfinger in US 6,436,953 claimed
tetrahydroimidazonaphthyridine compound useful for treatment of
gastrointestinal diseases.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the prior art compounds is that Senn-Bilfinger compounds in the tables have R' substituted a hydroxyl whereas the instant claims have a radical from which a hydroxyl group is formed under physiological conditions, such as the methyl carboxylate, ethyl carboxylate etc. as recited in the instant claims 5,8. The instant claims are therefore the prodrug of the hydroxyl-tetrahydroimidazonaphthyridine compounds of Senn-Belfinger et al. The preparation of the prodrug for enhanced solubility, delivery, and other pharmacokinetics is well known in the pharmaceutical art. It is generally taught by Bundgaard on the page 1 and 3, table 2 and specifically shown for various hydroxyl containing compounds, as in DE 4308095 (see English abstract), Schulte (5432183, see column 2, lines 9-39) and Aungst (4673679, see columns 11-12, table 1) wherein the prodrug of hydroxymorphinan lacks the bitter taste of the parent compound and enhances its bioavailability (abstract).

Finding of prima facie obviousness-rational and motivation (MPEP §2142.2143)

One having ordinary skill in the art would have been motivated to prepare the prodrug of the hydroxyl compound of Sen-Bilfinger et al. as taught by Bundgaard, DE 4308095, Schulte, US 5432183, and Aungst US 4673679 to arrive at the instant invention for enhanced delivery of the drug compounds.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy

reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 168 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130 (b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. *Claim Rejections - Obvious Double Patenting*

Claims 1-10 are provisionally rejected under the judicially created doctrine obviousness-type double patenting as being unpatentable over claims 1-10 of copending Application No. 10/182620 or claims 1-9 of copending Application No. 10/182654 or claims 1-15 of copending Application No. 10/103733 in view of Bundgaard et al. DE 4308095, Schulte et al. US 5432183, and Aungst US 4673679. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current invention claims are embraced by the invention claimed in the above patent.

Determination of the scope and content of the prior art (MPEP §2141.01)

Senn-Bilfinger in copending application 10/182620, 10/103733, 10/182654 claimed fused dihydropyran and tetrahydroimidazonaphthyridine compounds.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the prior art compounds is that Senn-Bilfinger compounds in the tables have R' substituted a hydroxyl whereas the instant claims have a radical from which a hydroxyl group is formed under physiological conditions, such as the methyl carboxylate, ethyl carboxylate etc. as recited in the instant claims 5,8. The instant claims are therefore the prodrug of the hydroxyl-tetrahydroimidazonaphthyridine compounds of Senn-Belfinger et al. The preparation of the prodrug for enhanced solubility, delivery, and other pharmacokinetics is well known in the pharmaceutical art. It is generally taught by Bundgaard on the page 1 and 3; table 2 and specifically shown for various hydroxyl containing compounds, as in DE 4308095 (see English abstract), Schulte (5432183, see column 2, lines 9-39) and Aungst (4673679, see columns 11-12, table 1) wherein the prodrug of hydroxymorphinan lacks the bitter taste of the parent compound and enhances its bioavailability (abstract).

Finding of prima facie obviousness-rational and motivation (MPEP §2142.2143)

One having ordinary skill in the art would have been motivated to prepare the prodrug of the copending hydroxy compound of Sen-Bilfinger et al. as taught by Bundgaard, DE 4308095, Schulte, US 5432183, and Aungst US 4673679 to arrive at the instant invention for enhanced delivery of the drug compounds.

This is provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 168 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130 (b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. *Claim Rejections - Obvious Double Patenting*

Claims 1-10 are provisionally rejected under the judicially created doctrine obviousness-type double patenting as being unpatentable over claims 1-7 of copending Application No. 10/485,514. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current invention claims are embraced by the invention claimed in the above patent.

Determination of the scope and content of the prior art (MPEP §2141.01)

Senn-Bilfinger in copending application 10/485,514 claimed compounds and compositions in the claims 1-7 as the same structural core formula with subset of Markush elements as the instant claims.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the prior art compounds are fully embraced each other.

Art Unit: 1625

Finding of prima facie obviousness-rational and motivation (MPEP §2142.2143)

The claims of the instant application and copending application contain enormous amount of overlapping subject matter. The overlapping subject matter is the result of the mix and matching the Markush elements from the broad scope. Mix and matching of Markush elements are considered prima facie obvious.

This is provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, In re Thorington, 418 F.2d 528, 168 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130 (b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Niloofar Rahmani whose telephone number is 571-272-4329. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm.

Art Unit: 1625

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NILOOFAR RAHMANI

12/01/2005

NR


D. MARGARET SEAMAN

PRIMARY EXAMINER

GROUP 1625